64. A process for making a vaccine composition for the use in the method of Claim 38, comprising admixing (a) an adjuvant composition comprising a surfactant of formula (I), (b) a pharmaceutically acceptable excipient, and (c) an antigen or antigenic composition.

REMARKS

Claims 1, 4-17, 35-38, and 34 are pending in the instant application. Claims 1, 4-17, 25-28, and 34 have been cancelled. Claims 38-64 have been added. In view of the following amendment and response, the Applicants believe the claims presented herein are allowable. Reconsideration is respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and the claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

The Applicants respectfully submit that the response to the office action dated 23 July 2002 (herein "Response") was fully responsive, and this was acknowledged as a *bone fide* reply by the Examiner. The grounds upon which the Examiner relies to make her arguments under paragraph (1), at page 2 of the Office Action, are based on inadvertent errors in a the Response made in a good faith effort to respond without deceptive intent. Moreover, the Applicants respectfully assert that the content or scope of the discretionary amendments made by the Applicants does not form a proper basis for a "not fully responsive" assessment. However, in an earnest effort to address the issues raised by the Examiner, the Applicants provide the following response and Supplementary Amendment.

At page 2, paragraph (1)(a) i), the Examiner asserts that the Response instructed claim 29 to be cancelled and for claims 25-28 to be amended. The Applicants withdraw this second request for cancellation of claims 29 and for amendment of claims 25-28.

At page 2, paragraph (1)(a) ii), the Examiner asserts that the Response instructed claim 38 and 39 to be amended. The Applicants withdraw this request for amendment.

At page 2, paragraph (1)(a) iii), the Examiner asserts that the Response instructed claim 40 and 41 to be cancelled. The Applicants withdraw this request for cancellation of claims 40 and 41.

At page 2, paragraph (1)(b), the Examiner alleges that original claims 1 and 22 were product claims, and that the instant claim 1, as amended in the Response, is a process claim. The Examiner further alleges that presentation of the originally presented invention for prosecution on the merits constitutes constructive election. The Applicants respectfully traverse this rejection. There was no prior formal Restriction Requirement made by the Examiner, and thus, no formal election of species could be or was made by the Applicants. The instant Office Action, solely, forms the basis to allege constructive election. This amounts to an informal, post-facto restriction requirement made after a first office action on the merits has begun. The Applicants posit that this is improper since claims to methods in the same art area existed since the time of filing of the application. New claim 38 (amended claim 1) is simply an additional method claim and is not a distinct invention for the purposes of proper restriction and election. It is as if the product claims were simply cancelled, without prejudice, and nothing more. The Applicants are entitled to cancel the product claims as well as to add additional method claims. Moreover, no new patentability determinations need be made in view of the addition of method claim to a further embodiment, *viz.*, claim 38, *et al.*

To facilitate prosecution and clarify the record, the Applicants herein cancelled claims 1, 4-17, 25-28, and 34 without prejudice and file herewith an amendment requesting entry of new claims 38-59.

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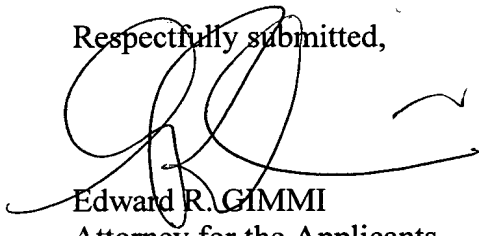
The Applicants request that no claims be withdrawn from consideration, other than those cancelled during prosecution.

The Applicants request reconsideration of the Response as well as consideration of the instant response to the Office Action and new claims.

The Applicants reserve the right to prosecute, in one or more patent applications, the claims as originally filed and any other claims supported by the specification. The Applicants thank the Examiner for the Office Action and consideration of this response. In view of the above amendment and remarks, which the Applicants believe are fully responsive to the outstanding Office Action, the Applicants respectfully request reconsideration of the rejected claims and allowance of all claims in the application. The Examiner is invited to contact the Applicants' undersigned attorney at the number provided below if this might facilitate prosecution of this case.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW WHERE CHANGES MADE

The following new claims have been added:

38. A method of raising an immune response in an individual against an antigen or antigenic composition, comprising administering intranasally to said individual a vaccine composition comprising an adjuvant composition and an antigen or antigenic composition; wherein the adjuvant composition is selected from the group consisting of: a non-vesicular aqueous solution and a suspension of a surfactant of formula (I):

$HO(CH_2CH_2O)_n$-A-R

wherein, *n* is 1-50, *A* is a bond or -C(O)-, *R* is C_{1-50} alkyl or Phenyl C_{1-50} alkyl.

39. A method of raising an immune response as claimed in Claim 38, wherein the surfactant of formula (I) is haemolytic.

40. A method of raising an immune response as claimed in Claim 38, wherein th adjuvant composition is characterized in that the surfactant of formula (I) is not in the form of a vesicle and also in that the degree of haemolytic activity is in the range of 0.05-0.0001% as measured in the Guinea Pig blood haemolysis assay.

41. A method of raising an immune response as claimed in Claim 39, wherein the surfactant of formula (I) has a haemolytic activity within a ten fold difference to that of polyoxyethylene-9 lauryl ether or polyoxyethylene-8 stearyl ether, as measured in the Guinea Pig blood haemolysis assay.

42. A method of raising an immune response as claimed in any one of the Claims 38 and 39-41, using an adjuvant that is a surfactant of formula (I), wherein *n* is 4 to 24.

43. A method of raising an immune response as claimed in Claim 38, wherein the adjuvant that is a surfactant of formula (I), wherein R is C_{8-20} alkyl or Phenyl C_{8-20} alkyl.

44. A method of raising an immune response as claimed in Claim 39, wherein the adjuvant that is a surfactant of formula (I), wherein R is C $_{8-20}$ alkyl or Phenyl C $_{8-20}$ alkyl.

45. A method of raising an immune response as claimed in Claim 40, wherein the adjuvant that is a surfactant of formula (I), wherein R is C $_{8-20}$ alkyl or Phenyl C $_{8-20}$ alkyl.

46. A method of raising an immune response as claimed in Claim 41, wherein the adjuvant that is a surfactant of formula (I), wherein R is C $_{8-20}$ alkyl or Phenyl C $_{8-20}$ alkyl.

47. A method of raising an immune response as claimed in Claim 42, wherein the adjuvant that is a surfactant of formula (I), wherein R is C $_{8-20}$ alkyl or Phenyl C $_{8-20}$ alkyl.

48. A method of raising an immune response as claimed in Claim 38 wherein n is 9, A is a bond or -C(O)-, R is C_{1-50} alkyl or Phenyl C_{1-50} alkyl and is characterized in that the surfactant of formula (I) is not in the form of a vesicle.

49. A method of raising an immune response as claimed in Claims 43 or 44, wherein R is C_{12} alkyl.

50. A method of raising an immune response as claimed in Claims 43, wherein R is C_{12} alkyl.

51. A method of raising an immune response as claimed in Claim 38 wherein n is 8, A is a bond or -C(O)-, R is C_{1-50} alkyl or Phenyl C_{1-50} alkyl and is characterized in that the surfactant of formula (I) is not in the form of a vesicle.

52. A method of raising an immune response as claimed in Claim 46, wherein R is C_{18} alkyl.

53. A method of raising an immune response as claimed in Claim 38, comprising a surfactant of formula (I), wherein A is a bond, thereby forming an ether.

54. A method of raising an immune response as claimed in Claim 38 comprising a surfactant of formula (I), wherein A is –C(O)-, thereby forming an ester.

55. A method of raising an immune response as claimed in Claim 38, wherein the polyoxyethylene ether or ester of formula (I) is selected from a group consisting of: polyoxyethylene 9-lauryl ether, polyoxyethylene-9-lauryl ester, polyoxyethylene-9-streary ether, polyoxyethylene-8-stearyl ether, polyoxyethylene-4-lauryl ether, polyoxyethylene-35-lauryl ether and polyoxyethylene-23-lauryl ether.

56. A method of raising an immune response as claimed in Claim 38, wherein the concentration of the surfactant is in the range of 0.1-10%.

57. A method of raising an immune response as claimed in Claim 38, wherein the concentration of the surfactant is in the range of 0.25-1%.

58. A method of raising an immune response as claimed in Claim 38, further comprising an antigen or antigenic composition.

59. A method of raising an immune response as claimed in Claim 38, wherein the antigen or antigen composition is derived from the group consisting of: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory syncytial virus, human paplloma virus, Influenza virus, Hib, Meningitis virus, Salmonella, Neisseria, Borrelia, Chalamydia, Bordetella, Streptococcus, Mycoplasma, Mycobacteria, Haemophilus, Plasmodium or Toxoplasma, IgE peptides such as the stanworth decapeptide and Tumor associated antigen (TMA) such as MAGE, BAGE, GAGE, MUC-1, Her-2 neu, LnRH, CEA, PSA, KSA, or PRAME.

60. A method of raising an immune response as claimed in Claim 38, wherein the vaccine comprises polyoxyethylene-9 lauryl ether and an influenza virus antigen.

61. A method of raising an immune response as claimed in Claim 38, wherein the vaccine is in the form of an aerosol or a spray.

62. A spray device, more particularly a bi-dose spray device, filled with a vaccine suitable for use in the method of raising an immune response as claimed in Claim 38.

63. A method of treatment, using the method of Claim 38, of a mammal suffering from or susceptible to a group of diseases consisting of: a pathogenic infection, cancer and allergy, comprising the intranasal administration of a safe and effective amount of a vaccine composition according to Claims 58-61.

64. A process for making a vaccine composition for the use in the method of Claim 38, comprising admixing (a) an adjuvant composition comprising a surfactant of formula (I), (b) a pharmaceutically acceptable excipient, and (c) an antigen or antigenic composition.